

3. *How long will I be in the study?*

The study includes 3 to 4 months of therapy and follow-up assessments at 4, 8, and 12 months. If your adolescent is in outpatient then your family will be in the study for 1 year. If your adolescent is in residential treatment, then your family will be in the study for approximately 1 year after the completion of the residential treatment.

4. *What will I have to do during the study?*

You will not have to do much more than if you decide not to take part in the study.

- Your child must be willing to attend all therapy sessions. If he or she is assigned to BSFT, at least two family members also need to attend.
- Agree to return for study follow-up visits and fill out questionnaires.
- Contact the clinic if you have any problems between visits.

5. *What happens at study follow-up visits?*

Study visits include questions about:

- Your child's health and how he or she is feeling.
- Drugs he or she is taking.
- How your child is doing in other areas (family/social, legal, employment, etc.).

You will be asked about:

- Services your child has received since you began the study.
- Who lives in your family.
- How you discipline, monitor, and control your child's behavior.

Study visits take 1-1 1/2 hours for parent(s)/guardian(s) and 2-3 hours for the child. Information about attendance and the therapy (called "tracking measures") is collected at more regular intervals in sessions that take about 10 minutes each.

6. *What will I get for taking part in the study?*

The therapies used in this study are designed to help your child reach his or her recovery goals. Information from this study may help others in the future. Participating families receive \$25 at the first assessment, \$35 at the second assessment, \$45 at the third assessment, \$55 at the fourth assessment, and \$10 for brief tracking measures. The total payment for a participant may be up to \$170. All payments are made directly to you, the parent(s)/guardian(s) participating in the assessment. Your child will receive movie passes for participating in the monthly drug use tests.

For More Information

For more information on the CTN, visit the NIDA website at www.drugabuse.gov.

For information on other clinical trials, the National Institutes of Health (NIH) has created a website to help patients, family members, and the general public obtain information about government-sponsored clinical trials. You may log on to www.Clinicaltrials.gov to learn about ongoing or new trials for all types of health-related conditions. The descriptions for individual trials include eligibility criteria, purpose of the trial, location, and how to apply if interested. The website is maintained and updated regularly by the National Library of Medicine.

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CTN-0014

Clinical Trials Network



Brief Strategic Family Therapy for Adolescent Drug Abusers

A research study
involving the family

Should we sign up?

Information for parents

NIDA NATIONAL INSTITUTE
ON DRUG ABUSE

NATIONAL INSTITUTES OF HEALTH
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Introduction

Your child has taken the first important step to recovery of his or her drug addiction by coming into treatment. And you want to make the best of it. By agreeing to join this research study, your family will help therapists find out how to best help other adolescents stop using drugs.

Description of the Study

Drug abuse is one of the most pressing problems facing teenagers in the United States. However, treatments such as Brief Strategic Family Therapy (BSFT) have been shown to dramatically impact drug use and related problems in young people. BSFT is a therapy that includes members of the family in the recovery process. It helps the family to understand and deal with your child and his/her problems.

The primary goal of this study is to examine the effectiveness of BSFT in the treatment of 12-17 year old drug abusers. The study looks at changes in drug use, problem behaviors, sexually risky behaviors, positive activities, involvement of family members, and family functioning.

If your family joins the study, your child will be assigned to get either:

- 12 to 16 sessions of BSFT over a 4-month period, plus up to 8 “booster” sessions, or
- Standard Treatment for a minimum of 3 to 4 months, plus booster sessions as required. Standard Treatment will vary depending on the regular activities at the agency.

Treatment in both conditions is provided in a setting such as a clinic, your home, or your child’s school.

If You Decide To Join

Your participation in this study is completely voluntary. You are encouraged to ask as many questions as you want to help you decide if you want to join the study. If you choose not to take part, your child’s treatment will not be affected in any way. If you do decide to participate, this is what you can expect:

1. After the study is fully described to you and your family, you will be asked for your written consent and your child will be asked for written “assent” (agreement) to participate in the study.
2. If your child is in outpatient treatment, you and your family will be asked for baseline information in the first 2 weeks after the consent/assent process. Then your child will be randomly selected to go into either BSFT or Standard Therapy (e.g., by the flip of a coin). This means that they cannot choose which therapy they will get. If you decide to join this study—you and your child must be willing to accept either type of therapy.
3. If your child is in residential treatment, the baseline assessment will be done in the first 2 weeks of treatment. Several weeks before discharge, a second assessment of substance use will be done. Your child will then be randomly selected to either BSFT or Standard Therapy. You and your child will be asked again for consent or assent. Therapy begins right after the assignment. All of the BSFT sessions will be videotaped. This occurs for four reasons: to make sure your therapist is following directions about the therapy, to help your therapist plan for future family sessions, to help the research team conduct future studies, and to help in the training of future therapists. The tapes will be kept in a locked, secure location and will be erased at the end of the study.

4. You will be asked to complete assessments similar to the baseline assessment 4, 8, and 12 months after therapy begins. Other information regarding the therapy, such as attendance, will also be collected at regular intervals. Your child will be asked about his/her drug use and will be tested for drugs in urine and in breath every month.
5. All of the information that you and your family give us will be kept confidential. The staff will explain the details of confidentiality to you.

Questions About the Study

The answers to these questions may help you decide if you and your child would like to participate in the study.

1. Who can participate?

Participants must be between 12 and 17 years old and have used illicit drugs other than alcohol or tobacco in the 30 days before the first assessment. Those in outpatient treatment must live with formal or informal “family.” Those in residential treatment must be expected to be discharged to live with their family. The family must live in the same geographical area as the treatment program. Other considerations:

- Special considerations apply for those who have considered suicide or who have current or pending legal charges.
- Adolescents in foster care cannot participate.

2. Who is considered family?

Family includes anyone who serves in the legal or traditional role of family members. All family members are encouraged to participate in the therapy. However, the consent of a biological parent or a legal guardian is required before an adolescent can participate.